REMARKS

Claims 3-5, 8, 23-33, 37-40, 42, and 45-47 are pending in the application. Claims 23-33, 37-40, and 42 are withdrawn as being drawn to non-elected inventions. Claims 3-5, 8, 45, and 46 are under active consideration.

Claims 5 and 8 have been amended to recite that the composition is an "immunogenic" composition. Claim 5 has been further amended to recite that the composition comprises an adjuvant. Support for these amendments can be found in the specification, for example, at page 25, line 3 through page 26, line 7; and page 56, line 10.

The foregoing amendments are made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications hereof containing the canceled or unamended claims.

35 U.S.C. § 102

A. Houghton

Claim 5 has been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Houghton et al. (International Patent Publication No. WO 91/15771; hereinafter "Houghton-1") or under 35 U.S.C. § 102(e) as allegedly being anticipated by Houghton et al. (U.S. Patent No. 5,683,864; hereinafter "Houghton-2"). Houghton-1 and Houghton-2 have been cited for teaching immunogenic compositions comprising HCV fusion polypeptides containing an HCV C (core) domain and at least one other HCV antigen selected from the group consisting of NS3, NS4, NS5, and S, wherein the NS5 is located in the range of amino acid residues 2054-2464. The Office Action further alleges that though Houghton-1 and Houghton-2 do not specifically mention pharmaceutically acceptable excipients, the buffer described as being used to store or dissolve fusion proteins in kits is a pharmaceutically acceptable excipient. Applicants respectfully traverse the rejection and the supporting remarks.

In particular, the present claims all pertain to immunogenic compositions including NS3, NS4, NS5a, NS5b and core polypeptides either as fusions (claims 3-5) or as individual components (claims 8, 45 and 46). The compositions further include a pharmaceutically

acceptable excipient, and an adjuvant. The cited art does not teach such compositions and therefore does not anticipate the claims.

To reiterate, in order to anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986). *Atlas Powder Co. v. E. I. du Pont De Nemours & Co.*, 224 USPQ 409, 411 (Fed. Cir. 1984). Moreover, the single source must disclose all of the claimed elements "arranged as in the claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); *Connell v. Sears Roebuck & Co.*, 220 USPQ 193, 198 (Fed. Cir. 1983). Finally, the law requires identity between the claimed invention and the prior art disclosure. *Kalman v. Kimberly-Clar Corp.* 218 USPQ 781, 789 (Fed. Cir. 1983, cert. denied, 465 U.S. 1026 (1984)).

Neither of Houghton-1 or Houghton-2 pertains to compositions that for inducing an immune response. Rather, the focus of Houghton-1 and Houghton-2 is on compositions for immunoassays and diagnostics, specifically, compositions that react with antibodies, as opposed to compositions that elicit antibody or T-cell responses. See, e.g., page 6, lines 13-16 of Houghton-1 and column 4, lines 5-8 of Houghton-2. Both references fail to describe any composition comprising an adjuvant that activates HCV-specific T cells. Therefore, claim 5 is not anticipated by Houghton-1 and Houghton-2 and withdrawal of this basis for rejection is respectfully requested.

B. Fields

Claims 5 and 8 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Fields et al. (U.S. Patent No. 7,052,696; hereinafter "Fields"). Fields has been cited for teaching an immunogenic composition comprising a mosaic polypeptide expressed as a fusion protein comprising "an antigenic epitope of HCV NS3 located in the range of amino acids 1471-1573" and antigenic epitopes containing "amino acid residues 1-91 (HCV core domain), amino acid residues 1789-1867 (HCV NS4), amino acid residues 1916-1948 (NS5a) and amino acid residues 2322-2423 (NS5b)." Office Action, page 4. The Office alleges compositions may also include a pharmaceutically acceptable carrier and an adjuvant and be used in a method to induce an immunological response against HCV and asserts that the locations of the nonstructural proteins are known in the art as evidenced by Clark et al. (*J. Gene. Virol.* (1997)

78:2397-2410, Fig. 1 at page 2398). Applicants respectfully traverse the rejection and the supporting remarks.

In particular, contrary to the Office's characterization of Fields, Fields does not disclose the use of NS5b in his mosaic polypeptides. A comparison of Fields' specified NS5 polypeptide with that of Choo et al., *Proc. Natl. Acad. Sci. USA* (1991) 88:2451-2455 (appended), shows that Fields' amino acids 2322-2423 of SEQ ID NO:5 actually occur at positions 2212-2313 of the HCV polyprotein and are therefore all contained within the NS5a region. See, Figure 1 of Choo and page 16, lines 15-18 of the present application. Fields does not disclose any composition that activates HCV-specific T cells comprising amino acid residues of NS5b. Rather, Fields describes compositions comprising antigenic epitopes from the core, NS3, and NS4 regions and optionally additional epitopes from the NS4 or NS5a regions (see, *e.g.*, abstract, col. 1, lines 60-64; and col. 4, lines 15-21). Since Fields fails to include NS5b in compositions, claims 5 and 8 are not anticipated by Fields.

For at least these reasons, withdrawal of the rejections under 35 U.S.C. § 102 is respectfully requested.

Nonstatutory Double Patenting

The Examiner has provisionally rejected claim 5 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 45 of copending U.S. Patent Application Serial No. 10,612,884. In particular, the Office Action alleges that claim 45 of copending U.S. Patent Application Serial No. 10/612,884 is directed to a composition comprising NS4, NS5, NS5a, NS5b, and a core antigen having defined amino acid sequences that could be considered to be species of the generically claimed HCV antigen polyproteins in claims 5 and 8 of the instant application (Office Action, page 5). Applicants request the rejection be held in abeyance until there is an indication of allowable subject matter in either application.

CONCLUSION

In light of the above remarks, Applicants submit that the present application is fully in condition for allowance. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned.

The Commissioner is hereby authorized to charge any fees and credit any overpayment of fees which may be required under 37 C.F.R. §1.16, §1.17, or §1.21, to Deposit Account No. 18-1648.

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